UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 1:01-CV-12257-PBS Sub-Category Case No. 1:08-CV-11200
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators* *v.* *Baxter Hemoglobin Therapeutics and Baxter International Inc.*	Judge Patti B. Saris

BAXTER INTERNATIONAL INC.'S SUPPLEMENTAL REPLY BRIEF IN FURTHER SUPPORT OF ITS MOTION TO DISMISS RELATORS' COMPLAINT

Discovery has only confirmed what Baxter has previously asserted -- Relators' action must be dismissed. Relators concede that Counts II, XII, XVI, XX, and XXI should be dismissed. Relators hoped to save the remaining counts[1] by pointing to carefully drafted, but purposely vague, declarations[2] and arguing that the False Claims Act's ("FCA") public disclosure bar does not preclude jurisdiction because they are "original sources." The sworn testimony of the Relators themselves does not support these assertions.

We now have deposed both Relators. Their sworn testimony, which we liberally cite below, contradicts their declarations. Greg Hamilton has sold himself to the AWP relators' market as a professional consultant in 10 to 25 cases against the pharmaceutical industry. Hamilton lacks any direct and independent knowledge supporting "his" allegations. Hamilton never worked for Baxter, and has no information or knowledge regarding Baxter's pricing decisions or price reporting. Hamilton's allegations are based entirely upon a telephone

[1] The remaining counts subject to the motion to dismiss are federal FCA and related state claims (Counts I, III-XI, XIII-XV, XVII-XIX, and XXI-XXIII). Baxter did not move to dismiss Sun's employment-related claims (Counts IV, V, VI, XXII, and XXIII).

[2] The Declarations referenced herein are attached to Relators' September 15, 2009 Memorandum in Opposition to Baxter's Motion to Dismiss ("Opp.," Sun Docket No. 72) and are referred to as, for example, "Sun Decl."

conversation with a First Databank ("FDB") employee and collateral research and investigation. Incredibly, Hamilton disagrees with the Complaint allegations and legal claims that were apparently supplied by the other Relator, Linnette Sun.

Sun was employed by Baxter, but she has no direct and independent knowledge of facts that support her FCA claims. She worked for Baxter for 13-months, during which time period she was principally involved with only two therapies, Advate and Aralast. Sun left Baxter in July 2003, before Advate was even approved for sale by the FDA. The Complaint contains no information about Aralast other than including its name in a list of Baxter drugs. Baxter did not acquire the rights to sell Aralast until October 2003, three months after Sun left Baxter. Sun therefore cannot have original source status with respect to either Advate or Aralast.

In reality, Relators' attorneys first introduced Hamilton and Sun to one another shortly before the Complaint was filed. Counsels' motivation for introducing Hamilton to Sun is clear: they hoped a Baxter insider – Sun – would cloak Hamilton's FDB hearsay with sufficient credibility to survive the public disclosure bar. The Court should reject their efforts and dismiss all FCA-related Counts.

I. THE FALSE CLAIMS ACT COUNTS MUST BE DISMISSED BASED ON THE PUBLIC DISCLOSURE BAR AND BECAUSE RELATORS ARE NOT ORIGINAL SOURCES.

Relators' Complaint includes two federal FCA Counts – Count I, which relates to WAC and AWP inflation, and Count III, which concerns Best Price reporting.[3] Neither Relator is an original source for these claims.

A. COUNT I – WAC/AWP-RELATED FALSE CLAIMS

Count I has been a moving target; Relators and their lawyers cannot seem to agree exactly what behavior it is meant to encompass. We previously demonstrated that the alleged

[3] The Complaint also has a number of state FCA and FCA-type counts, which should be dismissed for the same reasons and for procedural reasons discussed *infra* at 13-14.

AWP fraud/"marketing the spread" scheme was the subject of dozens of prior complaints and other public disclosures. *See* Baxter's August 14, 2009 Memorandum in Support of Its Motion to Dismiss ("Mem.;" Sun Docket No. 66) at 3-9; Baxter's September 30, 2009 Reply ("Reply;" Sun Docket No. 76) at 2-4. [4] Indeed, Sun admits that she was aware of these prior AWP suits and that they formed a basis for the Complaint. Sun Decl. ¶ 13. At deposition, Sun again admitted her knowledge of these pre-existing AWP lawsuits. Ex.[5] A, Transcript of the January 19, 2010 Deposition of Linnette Sun ("Sun Tr.") 80:8-16; 92:3-94:16; 95:8-98:19.[6] Hamilton, too, was aware of these pre-existing suits. Ex. B, Transcript of the January 21, 2010 Deposition of Greg Hamilton ("Hamilton Tr.") 101:1-103:3.

Acknowledging the prior disclosure bar, Relators' Opposition claimed that Relators were not seeking recovery based on this previously disclosed AWP scheme. Instead, the Opposition insisted that Relators' Complaint involved a "new species of AWP fraud," that "*could not even have existed before the reporting mechanism changed in 2000*." Opp. at 1 (emphasis added).[7] Relators' construct is that Baxter did not report a WAC to the publications

[4] In *United States ex rel. Ven-A-Care of the Florida Keys v. Actavis Mid Atlantic LLC* , Civ. A. No. 08-CV-10852-PBS, 2009 WL 3171798 (D. Mass. Oct. 2, 2009), this Court found that certain authorities that we have previously cited – such as GAO reports – were not public disclosures. While we disagree, Baxter has provided ample additional authority, including numerous prior complaints, which establish prior public disclosure.

[5] The Exhibits referenced herein are attached to the January 27, 2010 Declaration of Ruchi Jain, submitted in conjunction with this Supplemental Reply Brief.

[6] Sun tried to distinguish these earlier suits by alleging that they did not concern outpatient drugs such as those administered to patients by home healthcare agencies like Baxter's hemophilia therapies. Sun Tr. 121:3-124:17. As this Court is well aware, most of the prior AWP suits concerned drugs reimbursed under Medicare Part B, which includes drugs administered by physicians and home health care agencies. *See* Mem. at 5-6; Reply at 2-4. Furthermore, as discussed in prior briefing, the very types of Baxter hemophilia therapies Sun contends were not covered by prior AWP suits were, in fact, specifically named in those suits. *See* Mem. at 7 n.9, 17 n.14; Reply at 3-5.

[7] In the Complaint, however, Relators seek damages "from at least 1998 to the present." *See* Complaint ¶¶ 108, 117, 127, 137, 147, 157, 167, 178, 189, 200, 210, 220, 229, 238, 247. Hamilton seemed to concede that based on his understanding of Relators' theory of the case, damages could not start accruing before May 2000. Hamilton Tr. 98:15-100:19.

and instead supplied a "list price" that Baxter knew would be marked up to an "inflated" AWP. *See* Opp. at 1-3; Hamilton Decl. ¶ 8. In deposition, however, Sun partially rejected the "new species of AWP fraud" argument and, changing course yet again, argued that the case actually concerns two different types of AWP fraud – the first being the "marketing the spread"-type fraud alleged in prior AWP complaints, and the second involving FDB's 25% markup from WAC to AWP. Sun Tr. 113:5-114:18. Nothing in Sun's testimony supported the "new species" argument.

Notwithstanding Relators' flip-flops, all manner of AWP fraud – whether based on a markup from WAC or on straight AWP price reporting – is redundant of the prior complaints that alleged reimbursement was too high because of Baxter's allegedly inflated AWP. *See* Mem. at 4-6; Reply at 3-4. In addition, as described below, neither Relator has any direct or firsthand knowledge concerning the Complaint's WAC/AWP allegations. Thus, Relators do not meet the original source exception.

1. Hamilton

Hamilton never worked for Baxter. Hamilton Tr. 30:3-6. He did not know Sun until they were introduced by counsel shortly before the Complaint was filed. *Id.* 22:22-25:1; *see also* Sun Tr. 13:1-18:21. Hamilton is now a professional AWP consultant for relators; he presently is involved with 10 to 25 cases against the pharmaceutical industry.[8] Hamilton Tr. 9:2-21; 11:15-14:19.

Hamilton previously alleged that he gained information about Baxter pricing through "pricing discussions" during meetings with Baxter executives. Hamilton Decl. ¶¶ 2, 4-7. But the implication that Hamilton's "pricing discussions" with Baxter somehow relate to the allegations

[8] One of Hamilton's lawyers in this case, Mr. Kleiman, paid Hamilton approximately $120,000 for consulting services in another pharmaceutical case. Hamilton Tr. 14:20-15:17. Hamilton also has been proposed as an expert in another, unrelated product liability case against Baxter pending in Nevada.

in the Complaint is false. *See* Reply at 6-7; Reply Ex. F, Guiheen Decl. ¶¶ 5-11; Reply Ex. G, O'Malley Decl. ¶¶ 5-10. Hamilton has no real memory of any of the alleged meetings he had with Baxter officials. Hamilton Tr. 78:18-84:8; 96:25-98:9. For example, when asked about a page in his appointment book, Hamilton testified as follows:

> A. That probably means meeting with Baxter, Royal and possibly somebody else.
>
> Q. Okay. And where were you meeting with Royal on January 24th, 2005?
>
> A. I don't know.
>
> Q. Did you meet with them then?
>
> A. I can't say for certain. . . .
>
> Q. Do you remember what the subject of your meeting was at that time?
>
> A. No.

Id. 79:6-18.

> Q. If I ask you what happened, for example, at the National Hemophilia Foundation meeting. . . will you be able to tell me what occurred during that meeting?
>
> A. Specifically, no.
>
> Q. And will you be able to tell me what occurred at any of the meetings that are identified in any of these calendar pages?
>
> A. There may be – generally speaking the answer is no.

Id. 83:24-84:8.

> Q. And in the last sentence of paragraph 7 [of Hamilton's declaration] you reference, quote, numerous discussions with them about pricing strategies. Do you remember what the subject of those pricing discussions were in paragraph 7?
>
> A. I do not remember specific discussions.

Id. 98:4-9.

The conversations Hamilton does recall have nothing to do with the allegations in the Complaint. *Id.* 84:4-85:9; 89:9-98:9. As particularly concerns Advate, Hamilton's conversation with Baxter's Larry Guiheen involved Hamilton's assessment that the market price point for Advate was too high, which might inhibit sales and deter insurance companies from offering coverage:

> A. There is one conversation that I do remember very specifically. . . .
>
> And that was - - it was when we met with Larry Guiheen. And this was – oh, I'm going to guess this was within six months of Advate's launch. And I met with Larry at some sort of trade show. . . .
>
> So, we were in an exhibit hall, and we were talking about Advate. I expressed to Larry that my opinion that they had come out with, they'd launched too high of a premium for Advate over their other product and the comparable products, the recombinant products, that they came out just too high and they needed to drop that price.

Id. 91:25-92:15; s*ee generally id.* 91:19-93:12; 93:24-96:11. This conversation had nothing to do with any of the allegations in the Complaint.

Hamilton also is not an original source with respect to Baxter's WAC price reporting to FDB. By Hamilton's own admission, all of the facts underlying this theory emanated from (1) Kay Morgan, an FDB employee; (2) Hamilton's own examination of FDB materials; (3) research conducted with the assistance of employees of Hamilton's former employer, Express Scripts; and, (4) examination of the CMS website and other public sources of information. *Id.* 30:20-31:22; 35:20-46:3; 104:10-20[9]; *see also* Ex. C (December 20, 2009 Letter from Mark Kleiman to Merle DeLancey) at 2 ("We discussed that Hamilton's knowledge that is germane to these allegations came from Kay Morgan, a FirstData (*sic*) official."); Hamilton Decl. ¶¶ 8-10. For example, Hamilton testified as follows:

[9] Hamilton also conceded that much of his document production was not relevant to the Complaint and/or he did not know what the documents were or if he had ever seen them before. Hamilton Tr. 54:7-61:14; 73:3-77:2.

> Q. Let me refer you to paragraph 39 of the Complaint, which is Deposition Exhibit 7. Paragraph 39 begins with the following: "According to knowledge obtained by relator Greg Hamilton, FDB refused to accept Baxter's 'list sales price,' and instead submitted a letter stating that their list price was $1.31 and that they wanted their AWP to be described as $1.31." Do you see that?
>
> A. Yes, I do.
>
> . . . .
>
> Q. And was that information provided to you by Kay Morgan?
>
> A. Yes, it was.

Hamilton Tr. 43:3-17; *see also id.* 30:20-31:22 (source of information was FDB); 40:9-25 (sources of information were Express Scripts employees); 42:3-10 (source of information was CMS website).

Hamilton has no firsthand knowledge of any of the alleged WAC/AWP fraud. Direct knowledge is "'firsthand knowledge of the alleged fraud'" obtained through the relator's "'own labor unmediated by anything else.'" *United States ex rel. West v. Ortho-McNeil Pharm., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.)*, 538 F. Supp. 2d 367, 384 (D. Mass. 2008) (quoting *United States ex rel. Aflatooni v. Kitsap Physicians Servs.*, 163 F.3d 516, 525 (9th Cir. 1999)); *see also United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr.*, No. 4:05-CV-00899 GTE, 2007 WL 2904111, at *10 (E.D. Ark. Sept. 28, 2007) ("Direct and independent knowledge must be something more than 'secondhand information' or 'collateral research and investigations.'") (quoting *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995)).[10]

[10] In *Barth*, the court found that the relator did not have direct knowledge of the alleged fraud because he was acting as a union representative and "was, in effect, simply gathering information on behalf of the Union ... [and] [a]s such, he was a recipient of information and not a direct source." 44 F.3d at 704. The relator had obtained information "secondhand" – through intermediary sources, visits to the project job site, copies of publicly-filed payroll records, and interviews with employees. *Id*. at 703-4. The *Barth* court made a point of noting the intent behind the FCA: "[T]he Act seeks to encourage persons with '*first-hand* knowledge of fraudulent misconduct,' *Prudential*, 944 F.2d at 1154 (emphasis added), or those 'who are either

Hamilton's situation is very similar to that presented in *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87 (D. Mass. 2001), wherein a relator with alleged expertise who conducted his own research, including interviewing third parties, and then based his FCA claims on his research, was found not to be an original source. Similarly, the First Circuit recently found that a Relator whose information was gleaned from documents obtained in a FOIA request was not an original source, notwithstanding his alleged expertise. *United States ex rel. Ondis v. City of Woonsocket, et al.*, 587 F.3d 49 (1st Cir. 2009).

2. Sun

During her deposition, Sun described her responsibilities for only two products – Advate and Aralast. Sun Tr. 39:12-40:3; 45:6-49:17. Previously, she claimed primary responsible only for Advate. Opp. at 9; Sun Decl. ¶ 5. Sun indicated that she worked on pricing for other therapies, but she could not remember the names of most, and could provide no other specifics about the pricing of any other drugs. Sun Tr. 39:12-40:3; 48:10-49:17; 85:14-87:13; 91:13-19; *see also* Sun Decl. ¶ 5 (stating only that she "also did pricing for other Baxter products as well").[11] Advate is a third generation hemophilia factor, and other hemophilia factors were named in AWP complaints pre-dating Relators' Complaint. *See* Mem. at 7 n.9 and 17 n.14; Reply at 5. Sun left Baxter in July 2003, before Advate was even approved for sale by the FDA. Reply at 5-6 and Reply Exhibit F, Guiheen Decl. ¶ 9; *see also* Sun Tr. 47:1-21. Aralast is used to treat emphysema. Ex. D (October 20, 2003 Baxter Press Release Concerning Acquisition of Aralast). The Complaint contains absolutely no specifics about Aralast – no allegedly fraudulent

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close observers or *otherwise involved* in the fraudulent activity' to come forward. S.Rep. No. 345, 99th Cong., 2d Sess. 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5269 (emphasis added)." *Id*. at 703.

[11] Sun also mentioned seeing Best Price information for Recombinate, *see* Sun Tr. 83:13-84:3; 85:14-86:4; 91:3-16, but as described *infra* at 10-12, Sun has no direct knowledge of Baxter's Best Price calculations and submissions. These claims therefore lack jurisdictional foundation.

WAC or AWP, no transaction price, and no alleged spread. *See infra* at 12-13. And Baxter did not purchase Aralast until October 2003, three months after Sun left Baxter. Ex. D. Sun therefore cannot have original source status with respect to either Advate or Aralast. *See* Reply at 5-6 (citing *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 475 (2007); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100, 109 (D. Mass. 2008), *aff'd in part, rev'd in part*, 579 F.3d 13 (1st Cir. 2009)).

As concerns the "new species of AWP fraud," Sun's understanding of the FDB markup of WAC by 25% is based on her independent research comparing Redbook and FDB published prices and on conversations with persons at FDB whom she cannot identify. Sun Tr. 114:19-120:22; 128:5-133:17. Such independent research cannot form the basis of original source status. *See supra* at 7. Sun also claimed that FDB's 25% markup applied only to Baxter. Sun Tr. 120:15-22; 132:16 -133:14. Sun's position is obviously incorrect. *See New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 602 F. Supp. 2d 277, 280 (D. Mass. 2009) ("Beginning in 2001, FDB and McKesson reached a secret agreement to raise the markup between WAC and AWP from its standard 20% to 25% for over four hundred drugs."). Sun further testified that "a law" (which she could not identify) requires FDB to mark up WAC by 25%. Sun Tr. 125:17-126:7. This is also false and perhaps a misconstruction of the May 2000 consent decree between FDB and the U.S. Department of Justice ("DOJ"), whereby DOJ required that FDB independently verify manufacturers' AWPs. *See* Complaint ¶ 24; *see also* Hamilton Tr. 101:22-104:9. Sun's lack of understanding of this entire topic further demonstrates that she does not have direct or independent knowledge of any alleged fraud related to FDB's markup of Baxter's WAC prices.

B. COUNT III – BEST PRICE RELATED FALSE CLAIMS

Relators' Best Price-related FCA Count is predicated upon the "illegality" of Volume Committed Contracts ("VCCs"). *See generally* Complaint ¶¶ 49-51 and 53-61. Like WAC/AWP fraud, Best Price allegations and VCCs also were discussed in prior Complaints. *See* Mem. at 5-6; Reply at 2-3. Moreover, Relators have absolutely no direct or firsthand information regarding these allegations.

1. Hamilton

Hamilton readily admitted that he has no idea how Baxter calculated or reported Best Price and that he has no information that Baxter did so incorrectly:

> Q. Do you have any information that would suggest that Baxter failed to calculate best price in an appropriate way?
>
> A. No, I do not.

Hamilton Tr. 106: 17-20; *see generally id.* 106:5-20; 108:4-6. Hamilton testified that "first of all, this section [the allegations regarding Best Price and VCCs] comes from Linnette Sun." *Id.* 105:16-17; *cf. id.* 107:21-24. And, as described below, Hamilton completely disagrees with Sun's testimony about VCCs and thus *rejects the entire framework* for the Relators' Best Price-related FCA Count.

2. Sun

Sun admitted that she was not involved in the calculation of Best Price and does not know how this was done by Baxter. Sun Tr. 71:18-72:17; 76:2-15; 81:15-82:16; 84:8-88:12.[12] Sun also does not understand what goes into a Best Price calculation under 42 U.S.C. § 1396r-8(c)(1)(C); in fact, she took the position that to "calculate" Best Price is *per se* illegal. Sun Tr. 85:14-88:5. Sun claimed that she had found problems with Baxter's Best Price (and AWP) reporting for Recombinate and "other drugs," but when pressed she could not state the

[12] Also, because Sun left Baxter before any sale of Advate or Aralast, *see supra* at 8-9, she could not have seen any Best Prices for these drugs.

problem or offer any evidence or support. Sun Tr. 81:15-92:2; 99:5-105:12; *see also id.* 107:15-108:12 (regarding marketing the spread). Sun claimed only that she had given her counsel all the supporting documentation regarding these allegations. *Id.* 99:5-105:12; 156:2-157:2. No such documentation has been produced, although it clearly would have been responsive to Baxter's document requests to Relators. Sun's counsel, Kleiman, did produce some documents he represented belonged to Sun, but Sun did not know the source of any of these documents. *Id.* 34:14-37:19. When asked to find support for her assertion that Baxter's Best Price was false in the documents that her counsel had produced, Ms. Sun could not. *Id.* 99:5-105:12. And the only information that Sun could confirm she provided for the Complaint came from publicly available documents. *Id.* 137:4-139:7.

With particular respect to VCCs, Sun took the position that they are always "wrong." *Id.* 72:18-75:16; 76:16-80:16. Apparently, this "wrongness" has something to do with AWPs and marketing the spread, *id.* 72:18-73:5; 80:17-81:14, a practice clearly addressed in prior lawsuits and for which Sun has no direct and independent knowledge that she could articulate. *Id.* 134:17-136:15. Hamilton, however, strongly disagreed that there is anything wrong with or illegal about VCCs or giving customers rebates based on the volume of purchases:

> Q. Do you believe that there's something wrong about volume committed contracts?
>
> A. No.
>
> . . .
>
> Q. Okay. Then is there -- what is Baxter's practice regarding volume committed contracts that you believe give rise to best price or Stark violations?
>
> A. Well, first of all, let me say that this section comes from Linnette Sun.
>
> Q. Okay.
>
> A. Maybe that's – I've said enough.

> Q. No, I'm just trying to understand. It appears that something's wrong with volume committed contracts. And you said you don't think that anything's wrong with volume committed contracts.
>
> A. That's correct.

Hamilton Tr. 105:8-24; *se also id.*. 49:22-54:1; 105:1-106:4; 108:16-109:7. By Hamilton's own admission, Count III is baseless.

II. RELATORS' COMPLAINT ALSO IS INSUFFICIENT UNDER FED. R. CIV. P. 9(B).

For ten of the drugs allegedly at issue in the Complaint, Relators do nothing more than list them. *See* Mem. at 17 (citing Complaint ¶ 20). Relators' Complaint provides slightly more detail about two other Baxter drugs – Recombinate and Advate. Complaint ¶¶ 36-37, 39, 43; *see also* Opp. at 15 ("[The Complaint] details how Baxter misreported the price of Recombinate . . . and Advate."). However, this detail does not meet this Court's very clear standards:

> Specifically, this Court has held that a plaintiff must "state the specific drugs sold by each defendant by alleging the fraudulent scheme, specifying the allegedly fraudulent AWP figures for each drug, and attaching exhibits to the complaint to demonstrate the spread for each drug." *In re Pharm. Indus. Average Wholesale Price Litig.*, 178 F. Supp. 2d at 172.

United States ex rel. Ven-A-Care of the Florida Keys v. Actavis Mid Atlantic LLC, Civ. A. No. 08-CV-10852-PBS, 2009 WL 3171798 at * 8 (D. Mass. Oct. 2, 2009). In *Ven-A-Care*, the Complaint included: (1) "lists [of] the drugs at issue by Defendant, labeler code, name, dosage, and NDC," (2) "the fraudulent AWP and WAC figures for each drug," and (3) "the spread of each drug, both as a raw dollar amount and as a percentage." *Id.* In contrast, the Hamilton/Sun Complaint does not contain this information, with the exception of one allegedly false WAC for Recombinate (which is alternately described as either $1.30 or $1.31, *see* Complaint ¶¶ 36, 39), and an alleged false AWP for Advate of $1.60 (*see* Complaint ¶ 43). The Complaint has no

supporting proof of any actual transaction prices, and therefore does not demonstrate a spread for any drug. Fed. R. Civ. P. 9(b) requires dismissal of all FCA-related counts of the Complaint.

III. RELATORS DID NOT DISCLOSE THE INFORMATION THEY HAD TO GOVERNMENT OFFICIALS PRIOR TO FILING THEIR FCA SUIT.

Relators' counsel claims to have spoken with Michael Theis, an Assistant United States Attorney in the District of Colorado, prior to filing the Complaint. Opp. at 11; Kleiman Decl. ¶¶ 1-3. However, as Relators' document production makes clear, the only information provided to AUSA Theis pre-filing was: (1) a draft Complaint, Ex. E (February 10, 2005 email from Mark Kleiman to Michael Theis with attached draft complaint; GH001745-1827); *see also* Sun Tr. 146:9-147:12 and Sun Ex. 14 (draft complaint), and (2) an email with estimates of Baxter annual sales, Ex. F (February 12, 2005 email from Mark Kleiman to Michael Theis; GH001828). The draft complaint did not contain a Best Price Count. *Compare* Ex. E at 22 *with* Complaint ¶¶ 53-61; *see also* Sun Tr. 147:13-150:20. Relators therefore did not "voluntarily provide[] the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B).[13]

In his Declaration, Relators' counsel did not assert that he contacted any state personnel prior to filing this action. Kleiman Decl. ¶¶ 1-3. Relators produced no documents proving that they made any pre-Complaint disclosures to any state.[14] All claims under the state false claims acts of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts,

[13] On April 22, 2005, *after* Relators filed the Complaint, they provided AUSA Theis with two documents in support of their claims, an excerpt of prices from FDB and a Market Research Bureau Report on the Plasma Fractions Market. Ex. B, Hamilton Exhibits 20, 18, and 17 (Bates Nos. GH001525-001744).

[14] Sun testified that she met with some state Attorneys General, but could not recall which or whether these meetings were pre- or post-complaint. Sun Tr. 42:21-43:10. Hamilton could not recall any pre-Complaint meetings with federal or state government officials. Hamilton Tr. 27:2-28:7; 86:9-88:2.

New Mexico, Tennessee, Virginia, and the District of Columbia (the states remaining in the case after Relators' concessions) therefore must be dismissed for lack of jurisdiction. *See* Mem. at 18.

IV. RELATORS SHOULD NOT BE GIVEN LEAVE TO AMEND TO ADD ANTI-KICKBACK CLAIMS.

Admitting that they did not plead valid Stark Act claims, and thus agreeing to dismiss Count II of the Complaint, Relators now seek leave to add federal and state Anti-Kickback Act claims. Opp. at 20. According to Relators' Opposition, these counts would be based on the accusation that Baxter concealed discounts from CMS and underpaid rebates to the states. *Id.* However, Relators offered no testimony to indicate that they had any knowledge of any alleged kickback scheme. *See, e.g.*, Hamilton Tr. 108:7-14. Nor are any kickback-related facts or allegations included in the Complaint. Permitting amendment at this stage – nearly five years after the Complaint was filed –would unduly prejudice Baxter. Furthermore, based on their lack of knowledge and the absence of any facts supporting this new legal theory, Relators could never meet the requirements of Fed. R. Civ. P. 9(b), even if given leave to amend. Relators' request for leave to amend should be denied.

V. CONCLUSION

Relators' federal and state FCA claims should be dismissed because they are based upon prior public disclosures and neither Relator is an original source. Relators should not be given leave to plead Anti-Kickback Act claims. Because the only claims remaining are Sun's employment-related claims, we suggest that those claims be remanded to the District of Colorado. For the Court's convenience, a revised proposed Order is attached.

Respectfully submitted,

Dated: January 27, 2010	**/s/ Ruchi Jain** _____ J. Andrew Jackson Merle M. DeLancey Tina D. Reynolds Ruchi Jain **DICKSTEIN SHAPIRO LLP** 1825 Eye Street NW Washington, DC 20006 Telephone: (202) 420-2200 Facsimile: (202) 420-2201 *Admitted pro hac vice* Peter E. Gelhaar (BBO #188310) **DONNELLY, CONROY & GELHAAR, LLP** One Beacon Street, 33rd Floor Boston, MA 02108 Telephone: (617) 720-2880 Facsimile: (617) 720-3554 Counsel for Defendant Baxter International Inc.

CERTIFICATE OF SERVICE

I hereby certify that I, Ruchi Jain, an attorney, electronically filed the foregoing SUPPLEMENTAL REPLY BRIEF IN FURTHER SUPPORT OF BAXTER INTERNATIONAL INC.'S MOTION TO DISMISS RELATORS' COMPLAINT with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on January 27, 2009. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties. In addition, the individuals listed below were served a courtesy copy via U.S. Mail.

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